

REMARKS

This Amendment is in response to the Office Action dated September 27, 2007. The Amendments made herewith and the below Remarks are believed to place the application in condition for immediate allowance.

The rejections asserted under 35 Section 112, second paragraph, and 35 U.S.C. Section 101 are believed to have been mooted by means of this Amendment, including the cancellation of claim 55.

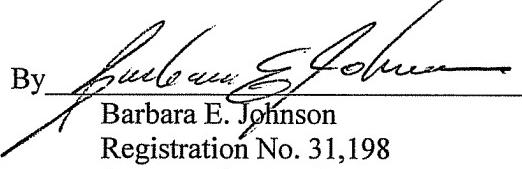
Regarding the asserted anticipation and obviousness rejections over Hallworth, Ganderton et al. and Dahl et al., all of record, none of the references discloses or suggests--even taken in combination--the key claimed feature of the present claims. An essential feature of the claims, recited in each independent and dependent claim now pending, is the positive method limitation of granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained. This language describes a process which gives improved results as described in the Examples in the specification. By contrast, Hallworth describes (column 4, paragraph 16) how "the preparation and storage of lactose pellets is desirably carried out under anhydrous conditions to obviate any adverse effects of free moisture," so the granulation in the presence of the instant fluid binding agent and subsequent drying is not disclosed or taught at all. Ganderton et al. disclose (in Example 1, for instance) that the lactose crystals were formed and washed in acetone and various ethanol washes prior to drying, but the concept of active drying is not suggested. Dahl et al. are silent as to the preparation of crystals or pellets for inhalation therapy, and the Dahl et al. general teachings of wet granulation and fluid bed drying do not provide any general or specific guidance to make the claimed excipient for dry powder inhalation giving a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%.

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Entry of this Amendment and allowance of all of claims 28-54 are respectfully requested.

Respectfully submitted,
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